

Message

From: Matthews, Keith [KMatthews@wiley.law]
Sent: 4/17/2020 3:29:37 PM
To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: Re: request related to section G for 93167-EUP-E

Eric,

Mike subsequently agreed to a 9:30 start time.

Hope that this is ok.

Best,

Keith

Sent from mobile device. Please excuse any typographic errors.

On Apr 17, 2020, at 11:27, Bohnenblust, Eric <Bohnenblust.Eric@epa.gov> wrote:

Keith,

I don't think it should matter much, since we already have the information we should only have to do a quick double check of the documents. Also since it is only a section G revision, you can send the document directly to me so if there are any issues with the portal on Monday we can work around them without much issue.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Matthews, Keith <KMatthews@wiley.law>
Sent: Friday, April 17, 2020 10:06 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Nathan Rose <nathan.rose@oxitec.com>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: request related to section G for 93167-EUP-E

Good morning Eric,

Given the timing, and the fact that this will necessitate submission of a revised Section G in advance of application approval, would it make sense to try to move Monday's call to an earlier time, to maximise the amount of time available for document production and submission?

Thanks,

Keith

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Friday, April 17, 2020 7:29 AM
To: Nathan Rose <nathan.rose@oxitec.com>; Matthews, Keith <KMatthews@wiley.law>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: request related to section G for 93167-EUP-E

Nathan,

Thanks for confirming.

Best.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>
Sent: Friday, April 17, 2020 7:23 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: request related to section G for 93167-EUP-E

Hi Eric

This doesn't change anything – thanks for checking though.

I'll add that detail to both of those sections, and will wait till our call on Monday in case you have any further requests, before submitting.

Best wishes

Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: 17 April 2020 12:11
To: Nathan Rose <nathan.rose@oxitec.com>; Matthews, Keith <KMatthews@wiley.law>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: request related to section G for 93167-EUP-E

Nathan,

Thanks for the clarification, I realized I mis-cited the egg and mortality sections in the following sentence. That sentence should have read: Can you confirm that the methods referenced in Sections 5.3.3, 5.11.2, 5.2.6.2/5.9.4.2 (The eggs and mortality assessment sections) are the methods/frequency that will be used for penetrance monitoring. Regardless I think you confirmed what we are asking, but let me know if this changes anything. In addition we have an additional request below.

In addition to the sentence you indicate adding to section 5.9.4.1, reference the egg and mortality sections (5.3.3, 5.11.2, 5.2.6.2/5.9.4.2) in sections 5.2.6.1/5.9.4.1 where you discuss penetrance testing.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
Phone: 703-347-0426
Email: Bohnenblust.eric@epa.gov

From: Nathan Rose <nathan.rose@oxitec.com>
Sent: Thursday, April 16, 2020 11:10 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Matthews, Keith <KMatthews@wiley.law>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Kevin Gorman <Kevin.Gorman@oxitec.com>
Subject: RE: request related to section G for 93167-EUP-E

Hi Eric

This understanding is correct.

- Fluorescence will be used as the screening method (5.2.6.1 and 5.9.4.1), screening larvae hatched from ovitraps (more detail on hatching methods in 5.3.3 and 5.11.2) in the trial areas.
- The sample size (number of ovitraps) and frequency of ovitrap monitoring is described for Trial A in Section 5.2.6.2 and for Trial B in Section 5.9.4.2.

When we resubmit section G, I will add a sentence to Section 5.9.4.1 to clarify this for Trial B, but will wait until Monday in case you have additional requests.

Kind regards
Nathan

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: 16 April 2020 15:55
To: Matthews, Keith <KMatthews@wiley.law>; Nathan Rose <nathan.rose@oxitec.com>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>
Subject: request related to section G for 93167-EUP-E

Keith and Nathan,

We have a request for some clarification related how Oxitec is assessing penetrance, which I think will be most easily addressed in the section G for the experimental program.

In Section 5.2.6.1, it is stated that fluorescence will be used to screen for penetrance. In the mortality assessment sections (5.3.3, 5.11.2) Oxitec provides the protocol for how penetrance can be assessed and in the eggs sections (5.2.6.2, 5.9.4.2) Oxitec provides information on the sample size/frequency in which penetrance can be assessed. Can you confirm that the methods referenced in Sections 5.2.6.1/5.9.4.1 (The eggs and mortality assessment sections) are the methods/frequency that will be used for penetrance monitoring. If these are not the methods/frequency used for penetrance monitoring could you provide additional detail on the methods/frequency that will be used for

penetrance monitoring. In addition please also make sure that the corresponding section for Trial B (5.9.4.1) also references the penetrance monitoring appropriately.

If you want to initially respond via email today or tomorrow to confirm or provide the details that is fine, then Monday at 10:30 we can touch base about submission of a revised section G in case we have any additional requests.

Thanks.

Eric Bohnenblust, Ph.D
Senior Biologist
Emerging Technologies Branch (ETB)
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Email: Bohnenblust.eric@epa.gov

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